UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.                                           | FILING DATE                             | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------|-----------------------------------------|----------------------|---------------------|------------------|
| 10/725,147                                                | 12/01/2003                              | William L. Howat     | CRD-5053 1765       |                  |
| 27777 7590 11/30/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON |                                         |                      | EXAMINER            |                  |
|                                                           |                                         |                      | SWEET, THOMAS       |                  |
|                                                           | N & JOHNSON PLAZ<br>VICK, NJ 08933-7003 | A                    | ART UNIT            | PAPER NUMBER     |
|                                                           |                                         |                      | 3774                |                  |
|                                                           |                                         |                      |                     |                  |
|                                                           |                                         |                      | MAIL DATE           | DELIVERY MODE    |
|                                                           |                                         |                      | 11/30/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Application No.                           | Applicant(s) |  |  |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|--|--|--|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 10/725,147                                | HOWAT ET AL. |  |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Examiner                                  | Art Unit     |  |  |  |  |
| •                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Thomas J. Sweet                           | 3774         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                           |              |  |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                           |              |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 M                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <u>arch 2007</u> .                        |              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |              |  |  |  |  |
| ·                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | , <del></del>                             |              |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                           |              |  |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |              |  |  |  |  |
| 4) Claim(s) <u>1-16</u> is/are pending in the application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                           |              |  |  |  |  |
| 4a) Of the above claim(s): 13-16 is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |              |  |  |  |  |
| 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |              |  |  |  |  |
| •                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 6)⊠ Claim(s) <u>1-12</u> is/are rejected. |              |  |  |  |  |
| 7) Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | r election requirement                    |              |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |              |  |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |              |  |  |  |  |
| 9)☐ The specification is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |              |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |              |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                           |              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                           |              |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                           |              |  |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                           |              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                           |              |  |  |  |  |
| 1. Certified copies of the priority documents have been received.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                           |              |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |              |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |              |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                           |              |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                           |              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                           |              |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Paper No(s)/Mail                          | Date         |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                           |              |  |  |  |  |
| Paper No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | o, <u> </u>                               |              |  |  |  |  |

10/725,147 Art Unit: 3774

## **DETAILED ACTION**

## Response to Arguments

Applicant's arguments filed 03/21/2007 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hoberman teaches forming Z pleats in both the radial and longitudinal direction of the tubular device to optimize the elongation and expansion of the device along the longitudinal axis thereof.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Application/Control Number:

10/725,147 Art Unit: 3774

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casey, II et al (USPAP 2004/0019375 A1) in view of Hoberman (4780344 or 5234727). Casey, II et al. disclose a prosthesis for maintaining lumen patency with all the elements of claims 1 and 12 except for the pleats being formed about the radial direction of the graft See Figures 1 and 6 for a prosthesis (10) comprising a substantially cylindrical hollow body (11) having a distal end (14) and a proximal end (15). See [0005], [0025], [0026] and [0028] for the body (11) being formed from a self-supporting, non-metallic graft material and at least a portion of the graft material including a plurality of pleats (17) disposed in a Z pattern. The pattern provides radial support to the body (11) while maintaining flexibility in a tubular organ. While Casey, II et al does not provide Z pleats in a combination of a radial and longitudinal pattern on the graft, Hoberman teaches forming Z pleats in both the radial and longitudinal direction of the tubular device to optimize the elongation and expansion of the device along the longitudinal axis thereof. It would have been obvious to one with ordinary skill in the art to modify the pleats of Casey, II et al to extend both longitudinally and radially along the elongated axis of the tubular graft to allow for expansion in both the radial and longitudinal direction of the device.

Claims 2-5, see Figures 1 and 6, lines 3-5 of [0028] and [0034] for distal and proximal anchors (61) in the form of metal support structures being connected to the distal (14) and proximal (15) ends, respectively.

Claims 6-8, see lines 4-6 of [0025] for the graft material being woven, non-woven or knitted.

Application/Control Number:

10/725,147

Art Unit: 3774

Claims 9-11, see lines 18-20 of [0025] for the graft material including polyester, polypropylene or polyethylene.

## Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. KURIBAYASHI et al (WO 02/078572).

This is a RCE of applicant's earlier Application No. 10/725147. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10/725,147

Art Unit: 3774

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet

Primary Examiner

AU 3774